

Support for IND1 polypeptides having a bHLH domain can be found on, e.g., page 9, lines 31-34 of the application.

Support for new claims 34-40 can be found on, e.g., page 17, lines 1-5, page 18, lines 1-3 and page 18, lines 13-14 of the present application. A declaration of Dr. Johan Botterman, Ph.D. accompanies this Amendment as evidence that the claimed IND1 fragments are useful to delay fruit dehiscence in plants. The declaration demonstrates that introduction of a 261 base pair fragment of the *Bn IND1* gene or a 269 base pair fragment of the *Bn IND2* gene into plants delayed fruit dehiscence in *Arabidopsis*. The *Bn IND1* and *Bn IND2* fragments had about 65% nucleotide identity with the corresponding fragments of SEQ ID NO:1. Accordingly, new claims 34-40 are allowable.

No new matter is added.

3. *Objection to sentence in "Cross-Reference To Related Applications"*

The sentence on page 1, lines 9-13 of the application was objected to because it is allegedly irrelevant. To address the Examiner's concerns the sentence is deleted from its present location under cross-reference to related applications and has been inserted in the detailed description. Applicants submit that the sentence is relevant because it incorporates related applications by reference.

4. *Objection to Drawings*

The draftsperson objected to the drawings. An appropriate response, with formal drawings, will be sent to the draftsperson concurrently.

5. *Claim Objections*

The Examiner objected to claim 8 because he alleged that the claim did not further limit claim 7 from which claim 8 depends. Claim 8 is canceled in this Amendment, thereby rendering the rejection moot.

6. *Rejection under 35 U.S.C. § 112, second paragraph*

Claims 5, 13-16, 20, 24-26, 31 and 32 were rejected under 35 U.S.C. § 112, second paragraph for reciting the phrase "polynucleotide sequence." Although Applicants disagree with the Examiner's interpretation of the phrase, the claims are amended herein to replace the phrase with the term "polynucleotide," as the Examiner suggests. Therefore, withdrawal of the rejection is respectfully requested.

In addition, claims 5 and 13 were rejected as unclear because the Examiner questioned whether "70% identity" referred to a polynucleotide or polypeptide sequence. Applicants thank the Examiner for noting this typographical error. As amended, claims 5 and 13 refer to polynucleotides encoding a polypeptide, wherein the polypeptide is at least 70% identical to SEQ ID NO:2.

7. *Rejection under 35 U.S.C. § 112, first paragraph*

Claims 1, 5, 9-19 and 29 were rejected under 35 U.S.C. § 112, first paragraph. According to the Examiner, the specification does not provide a description of the full scope of the claims.

Applicants respectfully traverse. Applicants submit that the Federal Circuit has held that the written description requirement can be fulfilled in any number of ways, so long as the specification describes the invention "in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention." *See University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997). For a chemical invention, an adequate description "requires a precise definition, such as by *structure*, formula, chemical name, or *physical properties*...." (emphasis added). Accordingly, as described below, the present specification provides ample written description for the pending claims, precisely as required by the Court in *University of California*.

In the present case, the amended independent claims 5, 13, and 20 are directed to methods or compositions encompassing a polynucleotide encoding a IND1 polypeptide at least 70% identical to SEQ ID NO:2, wherein the IND1 polypeptide

comprises a basic helix-loop-helix (bHLH) domain and introduction of the expression cassette into a plant to suppress IND1 expression results in a plant with delayed fruit dehiscence. IND1 polypeptides of amended claims are defined by identity to recited sequences and the presence of a bHLH domain. *See, e.g.*, page 9, line 29 to page 10, line 4 and page 11, line 26 to page 12, line 20 of the present application. Thus, the specification defines a *physical* and *structural property* of the invention, as explicitly required by the court in *University of California*.

Percent identity to a particular sequence reflects the relation of the nucleotide sequence to the recited sequence. Thus, the description of the claimed invention and the claim language satisfy the written description requirement as set forth by the court in *University of California* on at least two grounds, i.e. structural and physical properties.

Moreover, each claim only encompasses polynucleotides encoding polypeptides with a particular function, i.e., the ability to delay fruit dehiscence when introduced to suppress IND1 expression. Thus the amended claims are defined by *structure* and *function*.

As evidence that additional polynucleotides within the scope of the claims have the claimed function, i.e., the ability to delay fruit dehiscence, Applicants submit a Declaration of Martin F. Yanofsky, Ph.D., under 37 CFR § 1.132. The declaration demonstrates that two additional gene products from *Brassica napus* are at least 70% identical to SEQ ID NO:2 and have the same function as the Arabidopsis *IND1* gene product as demonstrated by complementation experiments. Therefore, the declaration confirms that the sequences recited in the present claims function as claimed.

Accordingly, Applicants therefore respectfully request withdrawal of the rejection.

8. *Rejections under 35 U.S.C. § 112, first paragraph*

A. Claims 12, 19 and 29

Claims 12, 19 and 29 were rejected as allegedly not enabled. The Examiner argued that there was no evidence that positions 1-2764 or 3362-3856 include promoter regulatory elements that function in a heterologous plant. Applicants respectfully traverse the rejection.

Claims 19 and 29 are canceled, thereby rendering the rejection of these claims moot. With regard to claim 12, Applicants note that the claim does not require activity in a heterologous plant. The claim is directed to an expression cassette. Therefore, the issues raised by the Examiner are not relevant to claim 12. Accordingly, Applicants respectfully request withdrawal of the rejection.

B. Claims 20-28 and 30-33

Claims 20-28 and 30-33 were rejected as allegedly not enabled. The Examiner asserted that there is no evidence that the described methods apply to plants other than Arabidopsis. In support of the rejection, the Examiner cited Quattrocchio *et al.* According to the Examiner, the art teaches that transforming plants with orthologous genes encoding bHLH transcription factors to produce a desired phenotype is unpredictable.

Applicants respectfully traverse the rejection. The basis of the Examiner's rejection appears to be the Quattrocchio *et al.* paper, which states that maize transcription factors C1 and R, or petunia transcription factors JAF13 and AN2, activate pigment expression in maize, but not in petunia.

The citation of Quattrocchio *et al.* is irrelevant because the claims are directed to suppression of expression of certain bHLH transcription factors, not to ectopic expression of bHLH transcription factors as described in Quattrocchio *et al.* The cited art only discussed the effect of positive expression (i.e., not co-suppression) of heterologous sequences in an attempt to complement mutations. The cited art does not comment in any way about the effect of suppression of expression of the C1, R, JAF13 or AN2 bHLH

transcription factors, let alone comment on any sequence described in the present application.

To the extent that one could speculate about the effects of suppression of the gene products described in Quattrocchio *et al.*, one would expect that suppression of expression of the C1, R, JAF13 or AN2 bHLH transcription factors would result in analogous phenotypes in their respective plants, i.e., a reduction of pigment production. There is no reason to believe that suppression of expression of the bHLH transcription factors would produce unpredictable phenotypes. Therefore, there is no basis for the Examiner's rejection. Accordingly, withdrawal of the rejection is respectfully requested.

C. Claims 24 and 26

Claims 24 and 26 were rejected as not enabled because the Examiner alleged that antisense-based gene suppression is unpredictable. Applicants respectfully traverse the rejection.

To establish a *prima facie* case of non-enablement, the Examiner must show that undue experimentation would be required to make and use the claimed invention. Even if the practice of the claimed invention requires a considerable amount of experimentation, it is not necessarily "undue" experimentation:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) (citing *In re Angstadt*, 190 USPQ 214 (CCPA 1976).
MPEP § 2164.06.

The thrust of the rejection's argument is that it is unpredictable what effect a heterologous antisense construct would have on a plant. *See*, Office Action, page 8. The Examiner argues that it would take undue experimentation to screen through transformants of all possible sequences encoding a polypeptide at least 70% identical to SEQ ID NO:2 to identify a plant with the desired phenotype. In fact, transformation and

screening of plants is routine in plant molecular biology. Indeed, plant molecular biologists commonly use antisense technology to reduce expression of gene expression. While such technology often requires screening of transformants to select plants with a desired phenotype, the screening is a routine part of laboratory work. In no way does the screening amount to undue experimentation. Thus, it is not an undue burden to screen through transformants to identify the desired phenotype. Withdrawal of the rejection is respectfully requested.

9. *Rejection under 35 U.S.C. § 102*

Claims 1-4 were rejected under 35 U.S.C. § 102 as allegedly anticipated by Ryan *et al.* With entry of this Amendment, claims 1-4 are canceled. Therefore, the rejection is moot and withdrawal of the rejection is requested.

10. *Rejection under 35 U.S.C. § 103*

Claims 1-19 were rejected under 35 U.S.C. § 103 as allegedly obvious over Ryan *et al.* in view of Quattrocchio *et al.* The examiner stated that Ryan *et al.* describes a polynucleotide having the sequence of SEQ ID NO:1 but does not describe an expression cassette or a plant comprising the expression cassette. However, the Examiner argues that it would have been obvious to make such compositions in light of Quattrocchio *et al.* because Quattrocchio *et al.* allegedly teaches an expression cassette encoding a bHLH transcription factor. Applicants respectfully traverse the rejection.

A proper obviousness rejection requires, *inter alia*, that the prior art: 1) provide a motivation for making the claimed invention, and 2) provide a reasonable expectation of successfully practicing the claimed invention. Both the motivation and the reasonable expectation of success must be founded in the prior art, not in Applicant's disclosure. *In re Vaack*, 20 USPQ2d 1438 (Fed. Cir. 1991). The Federal Circuit has recently restated the significance of the longstanding prohibition against the PTO's use of an applicant's disclosure as a recipe from which to choose references that describe each of the ingredients:

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"). *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999).

The Court stated that "actual evidence" of a motivation to combine references is required, "[t]hat is, the showing must be clear and particular. *See, e.g., C.R. Bard*, 157 F.3d at 1352, 48 USPQ2d at 1232. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *Id.*

Applicants respectfully submit that the instant rejection does not satisfy the requirement of providing actual evidence of a motivation to combine the cited references. While Quattrocchio *et al.* may describe expression cassettes encoding bHLH transcription factors, neither reference provides any reason for constructing an expression cassette comprising the sequence described in Ryan *et al.* Ryan *et al.* only provides a genomic sequence with little annotation. Quattrocchio *et al.* describes **other** bHLH sequences, but provides no reason to believe that **all** bHLH sequences would produce the same phenotypes as described in the reference. Indeed, as the present application demonstrates, IND1 plays a role in fruit dehiscence, not the pigmentation discussed in Quattrocchio *et al.* There is no reason for one of skill in the art to ascribe any function to the Ryan *et al.* sequence and therefore no reason described in the cited art for constructing an expression cassette comprising the sequence. Accordingly, the Examiner has not set forth a *prima facie* case of obviousness. Applicants therefore respectfully request withdrawal of the rejection.

CONCLUSION

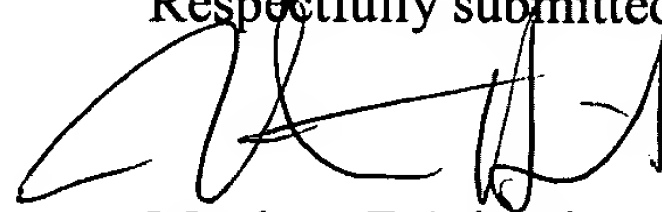
In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

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If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415 273-7554.

Respectfully submitted,



Matthew E. Hinsch
Reg. No. 47,651

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: (415) 576-0300
MEH:meh
SF 1386805 v1



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APPENDIX A

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The paragraph on page 1, lines 6-13 of the application now reads as follows:

This application is a continuation-in-part of U.S. Application Serial No. 09/339,998, filed on June 25, 1999, which claims benefit of priority to U.S. Provisional Application No. 60/090,649, filed June 25, 1998, each of which is incorporated by reference in its entirety. [This application is also related to U.S. Application Serial No. 09/349,677, filed July 8, 1999, which is a divisional application of U.S. Application Serial No. 09/067,800, filed April 28, 1998, which claims the benefit of priority of U.S. Provisional Application No. 60/051,030, filed June 27, 1997, each of which is incorporated by reference in its entirety.]

IN THE CLAIMS:

5. (Amended) An expression cassette comprising a promoter operably linked to a heterologous [an] IND1 polynucleotide [sequence], or a complement thereof, encoding an IND1 polypeptide, wherein:

the IND1 polypeptide is at least about 70% identical to SEQ ID NO:2 [1];

the IND1 polypeptide comprises a basic helix-loop-helix (bHLH) domain;

and

introduction of the expression cassette into a plant to suppress IND1 expression results in a plant with delayed fruit dehiscence.

13. (Amended) A plant comprising a recombinant expression cassette comprising a promoter operably linked to a polynucleotide [sequence] encoding an IND1 polypeptide, wherein:

the IND1 polypeptide is at least about 70% identical to SEQ ID NO:2 [1];

and

the IND1 polypeptide comprises a basic helix-loop-helix (bHLH) domain.

14. (Amended) The plant of claim 13, wherein the polynucleotide [sequence] encoding the IND1 polypeptide is operably linked to the promoter in the antisense orientation.

15. (Amended) The plant of claim 13, wherein the polynucleotide [sequence] encoding the IND1 polypeptide is operably linked to the promoter in the sense orientation.

16. (Amended) The plant of claim 15, wherein the polynucleotide [sequence] further comprises a second polynucleotide sequence encoding the IND1 polypeptide wherein the second polynucleotide [sequence] is operably linked to a second promoter in the antisense orientation.

20. (Amended) A method of delaying fruit dehiscence in a plant, the method comprising suppressing expression of an IND1 nucleic acid in the plant by introducing into the plant a recombinant expression cassette comprising a promoter operably linked to a polynucleotide [sequence] encoding an IND1 polypeptide at least about 70% identical to SEQ ID NO: 2, wherein the IND1 polypeptide comprises a basic helix-loop-helix (bHLH) domain.

24. (Amended) The method of claim 20, wherein the polynucleotide [sequence] encoding the IND1 polypeptide is operably linked to the promoter in the antisense orientation.

25. (Amended) The method of claim 20, wherein the polynucleotide [sequence] encoding the IND1 polypeptide is operably linked to the promoter in the sense orientation.

26. (Amended) The method of claim 25, wherein the polynucleotide [sequence] further comprises a second polynucleotide sequence encoding the IND1 polypeptide wherein the second polynucleotide [sequence] is operably linked to a second promoter in the antisense orientation.

APPENDIX B

CLAIMS PENDING WITH ENTRY OF AMENDMENTS

5. (Amended) An expression cassette comprising a promoter operably linked to a heterologous IND1 polynucleotide, or a complement thereof, encoding an IND1 polypeptide, wherein:

the IND1 polypeptide is at least about 70% identical to SEQ ID NO:2;

the IND1 polypeptide comprises a basic helix-loop-helix (bHLH) domain;

and

introduction of the expression cassette into a plant to suppress IND1 expression results in a plant with delayed fruit dehiscence.

6. The expression cassette of claim 5, wherein the IND1 polypeptide comprises SEQ ID NO:2.

7. The expression cassette of claim 5, wherein the IND1 polynucleotide comprises positions from about 2765 to about 3361 of SEQ ID NO 1.

8. The expression cassette of claim 7, wherein the IND1 polynucleotide comprises SEQ ID NO 1.

9. The expression cassette of claim 5, wherein the promoter is constitutive.

10. The expression cassette of claim 5, wherein the promoter is tissue specific.

11. The expression cassette of claim 10, wherein the promoter is a dehiscence zone specific promoter.

12. The expression cassette of claim 11, wherein the promoter comprises positions from about 1 to about 2764 or from about 3362 to about 3856 of SEQ ID NO:1.

13. (Amended) A plant comprising a recombinant expression cassette comprising a promoter operably linked to a polynucleotide encoding an IND1 polypeptide, wherein:

the IND1 polypeptide is at least about 70% identical to SEQ ID NO:2; and
the IND1 polypeptide comprises a basic helix-loop-helix (bHLH) domain.

14. (Amended) The plant of claim 13, wherein the polynucleotide encoding the IND1 polypeptide is operably linked to the promoter in the antisense orientation.

15. (Amended) The plant of claim 13, wherein the polynucleotide encoding the IND1 polypeptide is operably linked to the promoter in the sense orientation.

16. (Amended) The plant of claim 15, wherein the polynucleotide [sequence] further comprises a second polynucleotide sequence encoding the IND1 polypeptide wherein the second polynucleotide is operably linked to a second promoter in the antisense orientation.

17. The plant of claim 13, wherein lignification is reduced in valve margin cells.

18. The plant of claim 13, wherein the promoter is a dehiscence zone-selective regulatory element.

20. (Amended) A method of delaying fruit dehiscence in a plant, the method comprising suppressing expression of an IND1 nucleic acid in the plant by introducing into the plant a recombinant expression cassette comprising a promoter

operably linked to a polynucleotide encoding an IND1 polypeptide at least about 70% identical to SEQ ID NO: 2, wherein the IND1 polypeptide comprises a basic helix-loop-helix (bHLH) domain.

21. The method of claim 20, wherein the IND1 polypeptide comprises SEQ ID NO:2.

22. The method of claim 20, wherein the IND1 polynucleotide comprises positions from about 2765 to about 3361 of SEQ ID NO:1.

23. The method of claim 20, wherein the IND1 polynucleotide comprises SEQ ID NO:1.

24. (Amended) The method of claim 20, wherein the polynucleotide encoding the IND1 polypeptide is operably linked to the promoter in the antisense orientation.

25. (Amended) The method of claim 20, wherein the polynucleotide encoding the IND1 polypeptide is operably linked to the promoter in the sense orientation.

26. (Amended) The method of claim 25, wherein the polynucleotide further comprises a second polynucleotide sequence encoding the IND1 polypeptide wherein the second polynucleotide is operably linked to a second promoter in the antisense orientation.

27. The method of claim 20, wherein lignification is reduced in valve margin cells.

28. The method of claim 20, wherein the promoter is a dehiscence zone-selective regulatory element.

30. The method of claim 20, wherein the recombinant expression cassette is introduced into the plant using *Agrobacterium*.

34. (New) An expression cassette comprising a heterologous promoter operably linked to polynucleotide, or a complement thereof, wherein the polynucleotide is at least 65% identical to at least 200 contiguous nucleotides of SEQ ID NO:1, wherein introduction of the expression cassette into a plant to suppress IND1 expression results in a plant with delayed fruit dehiscence.

35. (New) The expression cassette of claim 34, wherein the polynucleotide is identical to at least 200 contiguous nucleotides of SEQ ID NO:1.

36. (New) The expression cassette of claim 34, wherein the polynucleotide is at least 500 nucleotides.

37. (New) The expression cassette of claim 34, wherein the polynucleotide is in a sense orientation with the promoter.

38. (New) The expression cassette of claim 34, wherein the promoter is constitutive.

39. The expression cassette of claim 34, wherein the promoter is tissue specific.

40. The expression cassette of claim 34, wherein the promoter is a dehiscence zone specific promoter.